

### **REMARKS**

The Office Action mailed October 7, 2005 has been received and reviewed. Claims 1-36 are pending in the application. Claims 12-21, 26-33, 35 and 36 were not considered in the Office Action. Claims 1-11, 22-25 and 34 each stand rejected. Claims 1, 6, 22-24 and 34 have been amended. Claims 2-5, 7 and 23 have been canceled. The application is to be amended as previously set forth. All amendments are made without prejudice or disclaimer. No new matter has been added. Reconsideration is respectfully requested.

#### **Election/Restriction**

The restriction requirement upon claims 1-33 was made final. Previously presented claims 35-36 were restricted to Group II and previously presented claim 34 was restricted to Group I. Applicant traverse the restrictions, and respectfully request that the method claims (Group IV, V, VI and VII) be rejoined upon allowance of the elected product claims (Group I).

#### **Information Disclosure Statement**

The references listed in the Specification mainly provide background information for better understanding of the art. Applicants believe that relevant references in this list had been included in the Information Disclosure Statement (IDS) and Supplemental IDS filed previously, and thus already considered by the Examiner.

#### **Claim Objections**

Claim 22 was objected to for allegedly being partially drawn to a non-elected invention. Claim 22 is amended in an effort to render the objection moot.

#### **Claim Rejections - 35 USC 112**

Claim 6 was rejected for allegedly being indefinite for failing to particular point out and distinctly claim the subject matter which applicants regard as the invention. Claim 6 has been amended to specifically recite a sequence comprising nucleotides 142-829 of SEQ ID NO: 5 or a functional fragment thereof. Applicants respectfully submit that the amended claim is clear and definite.

**Claim Rejections - 35 USC 102**

The present invention relates, among other things, to the finding that certain proteins are able to associate with apoptin. The present application describes a protein called “apoptin-associating protein 1” and is abbreviated as “AAP-1” (paragraph [0019] of the Specification). Moreover, the present application discloses that AAP-1 is able to provide apoptosis in cells, such as tumor cells, or other over-proliferating cells (paragraph [0024] of the Specification). Paragraph [0082] and Figure 4 further more disclose that co-expression of apoptin and AAP-1 in human tumor cells results in a faster apoptotic process than expression of apoptin or AAP-1 alone.

The amended claims are directed to a nucleic acid sequence encoding AAP-1 and apoptin. Basis for the amended claims can be found throughout the Specification. Basis for amended claim 1 can, for example, be found in paragraph [0011] and [0082] in the Specification. The term “a functional fragment or a functional equivalent thereof” refers to a fragment or an equivalent of AAP-1 that is capable of providing apoptosis (Specification, paragraph [0018]). The application, for example, discloses in Figure 1 (SEQ ID NO: 4) a nucleic acid (designated AAP-1-a) encoding a partial AAP-1 protein (lacking N-terminal amino acids compared to the AAP-1 protein encoded by Figure 2 (SEQ ID NO: 5)). It is clear from paragraph [0081] that the partial protein as well as the full-length protein are able to induce apoptosis.

Claims 1-11, 22-25 and 34 were rejected in the Office Action under 35 U.S.C. § 102. A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single reference which qualifies as prior art under 35 U.S.C. § 102. *Verdegaal Brothers v. Union Oil Co. of California*, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). The identical invention must be shown in as complete detail as is contained in the claim. *Richardson v. Suzuki Motor Co.*, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989). Applicants respectfully submit that claims 1-11, 22-25 and 34 are not anticipated by the references cited.

Garcia or Deposit AF101779

Claims 1-4, 6-11 and 22-25 were rejected under 35 USC § 102 (b) as allegedly being anticipated by Garcia et al. (“Garcia”) or Deposit AF101779. Garcia discloses the amino acid sequence of RYBP. Deposit AF101779 discloses a nucleotide sequence encoding RYBP and the

translated sequence of RYBP. Applicants have amended independent claim 1 to specifically include a novel apoptin-associating protein (AAP-1) (position 23-250 of SEQ ID NO: 6). RYBP may share homology with AAP-1, but the two proteins are not identical. Stretches of homology which are 100% homologous should not be considered to anticipate the nucleic acid sequence claimed, as “stretches” of a nucleotide or amino acid sequence are not the sequence “as a whole”. In other words, there are “stretches” of the sequences that are neither 100% homologous nor homologous at all. Since the sequence claimed is not identical to that of the RYBP disclosed in the references, it is irrelevant whether or not RYBP has an inherent ability to induce apoptosis. Therefore, neither Garcia nor Deposit AF101779 anticipates each and every element of amended independent claim 1, as would be required to maintain the 35 U.S.C. § 102(b) rejection thereof.

It is respectfully submitted that amended independent claim 1 is not anticipated because it recites a novel apoptin-associating protein. Claims 2-4, 7 and 23 have been canceled, rendering the rejections as to them moot. Claims 6, 8-11, 22, 24 and 25 are each not anticipated, among other reasons, for depending directly or indirectly from claim 1, which is not anticipated.

Deposit AI627241

Claims 1-11 and 22-25 were rejected under 35 USC § 102 (b) as allegedly being anticipated by Deposit AI6277241. Applicants respectfully submit that Deposit AI6277241 could not be found in relevant databases. Deposit AI627241 discloses a cDNA termed human YY1-Associates factor. Applicants reply to the rejections as understood.

Applicants have amended independent claim 1 to specifically include a novel apoptin-associating protein (AAP-1) (positions 23-250 of SEQ ID NO: 6). Although the cDNA sequence disclosed by Deposit AI6277241 may share homology with the nucleic acid sequence encoding AAP-1, the two sequences are not identical. Stretches of homology which are 100% homologous should not be considered to anticipate the nucleic acid sequence claimed, as “stretches” of a nucleotide or amino acid sequence are not the sequence “as a whole”. In other words, there are “stretches” of the sequences that are neither 100% homologous nor homologous at all. Since the sequence claimed is not identical to that of Deposit AI627241, it is irrelevant whether or not the sequence of Deposit AI627241 has an inherent ability to induce apoptosis. Therefore, Deposit

AI627241 do not anticipate each and every element of amended independent claim 1, as would be required to maintain the 35 U.S.C. § 102(b) rejection thereof.

It is respectfully submitted that amended independent claim 1 is not anticipated because it recites a novel apoptin-associating protein. Claims 2-5, 7 and 23 have been canceled, rendering the rejections as to them moot. Claims 6, 8-11, 22, 24 and 25 are each not anticipated, among other reasons, for depending directly or indirectly from claim 1, which is not anticipated.

US2003 0073623 A1

Claims 1-11 and 22-25 were rejected under 35 USC § 102 (e) as allegedly being anticipated by US2003 0073623 (Serial number 09/918995). US application 09/918995 was filed on July 30, 2001. Neither the Patent Application Information Retrieval system at the USPTO website nor the Specification of the published document indicates US application 09/918995 resulted from or claim benefits of any other earlier applications. The 35 U.S.C. § 102(e) date of a reference that did not result from, nor claim the benefit of, an international application is its earliest effective U.S. filing date, taking into consideration any proper benefit claims to prior U.S. applications under 35 U.S.C. § 119(e) or 120 if the prior application(s) properly supports the subject matter used to make the rejection in compliance with 35 U.S.C. § 112, first paragraph. *See* MPEP § 706.02(f). Therefore, the effective filing date of US application 09/918995 is July 30, 2001. The instant application was filed on September 5, 2000, which is earlier than the effective filing date of US2003 0073623. As such, US2003 0073623 should not qualify as a 102(e) reference.

Even if US2003 0073623 qualified as a 102(e) reference, applicants respectfully submit that the amended claims are patentable over the subject matter disclosed in US2003 0073623. US2003 0073623 discloses a nucleotide sequence (SEQ ID NO: 24859) with a length of 502 nucleotides. The nucleic acid sequences disclosed in the instant application are either much shorter or much longer than SEQ ID NO: 24859 disclosed in US2003 0073623. SEQ ID NO: 1 disclosed in the instant application has only 17 nucleotides. SEQ ID NO: 4 and SEQ ID NO: 5 disclosed in the instant application have over 900 nucleotides. The Office Action does not specify which sequence disclosed in the instant application shares a 96% homology with SEQ ID NO: 24859 of US2003 0073623. SEQ ID NO: 24859 of US2003 0073623 may have short

stretches of sequences conserved with some of the sequences disclosed in the instant application. However, judging by the sequence length alone, it is highly unlikely that SEQ ID NO: 24859 of US2003 0073623 would share a 96% homology with any of the sequences disclosed in the instant application.

Moreover, applicants have amended independent claim 1 to specifically include a novel apoptin-associating protein (AAP-1) (position 23-250 of SEQ ID NO: 6). Although SEQ ID NO: 24859 may share short stretches of homology with the nucleic acid sequence encoding AAP-1, the two sequences are not identical. Stretches of homology which are 100% homologous should not be considered to anticipate the nucleic acid sequence claimed, as “stretches” of a nucleotide or amino acid sequence are not the sequence “as a whole”. In other words, there are “stretches” of the sequences that are neither 100% homologous nor homologous at all. Since the sequence claimed is not identical to SEQ ID NO: 24859 disclosed in the reference, it is irrelevant whether or not SEQ ID NO: 24859 has an inherent ability to induce apoptosis. Therefore, US2003 0073623 does not anticipate each and every element of amended independent claim 1, as would be required to maintain the 35 U.S.C. § 102(e) rejection thereof.

It is respectfully submitted that the amended independent claim 1 is not anticipated because it recites a novel apoptin-associating protein. Claims 2-5, 7 and 23 have been canceled, rendering the rejections as to them moot. Claims 6, 8-11, 22, 24 and 25 are each not anticipated, among other reasons, for depending directly or indirectly from claim 1, which is not anticipated.

#### Double Patenting

Claims 1-11, 22-25 and 34 were rejected under the judicially created doctrine of obviousness type double patenting in view of US Patent 6,809,189 B2. Applicants have amended independent claim 1 to specifically include a novel apoptin-associating protein (AAP-1) (position 23-250 of SEQ ID NO: 6), which would not be anticipated by the species of AAP disclosed and claimed in ‘189. It is respectfully submitted that amended independent claim 1 is not anticipated because it recites a novel species of apoptin-associating protein. Claims 2-5, 7 and 23 have been canceled, rendering the rejections as to them moot. Claims 6, 8-11, 22, 24 and 25 are each not anticipated, among other reasons, for depending directly or indirectly from claim 1, which is not anticipated.

**CONCLUSIONS**

Entry of the amendments and reconsideration of the rejections and objections is respectfully requested. If questions should remain after consideration of the foregoing, the Examiner is kindly requested to contact applicants' agent at the address or telephone number given herein.



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